

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q86306

Nobuhiko FUSHIMI, et al.

Allowed: April 17, 2009

Appln. No.: 10/525,197

Group Art Unit: 1623

Confirmation No.: 7757

Examiner: Eric OLSON

Filed: February 22, 2005

For: PYRAZOLE DERIVATIVES, MEDICINAL COMPOSITION CONTAINING THE  
SAME, MEDICINAL USE THEREOF, AND INTERMEDIATE FOR PRODUCTION  
THEREOF

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705**

**MAIL STOP PATENT EXTENSION**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Applicant requests reconsideration of the Director's determination of patent term adjustment (PTA) as communicated in the Notice of Allowance mailed on April 17, 2009. In particular, Applicant requests the correction of the PTA from 479 days, as indicated in the Notice of Allowance, to 946 days plus the amount of days beginning on the date following the filing of this Application for Patent Term Adjustment (hereinafter "Application"), until the date the '197 Application issues as a patent, as discussed in the Application, below.

In accordance with 37 C.F.R. § 1.705(b), this Application for Patent Term Adjustment is being filed no later than the payment of the Issue Fee and is therefore timely filed. The Director is authorized to charge Applicant's Deposit Account 19-4880 for the required fee as specified in 37 C.F.R. § 1.18(e) (\$200.00).

As required by § 1.705(b)(2), a Statement of the Facts is set forth below. For the purposes of clarity, references to “this Application” refer to the present Application for Patent Term Adjustment, whereas references to “the ‘197 Application” refers to U.S. Application No. 10/525,197.

## **I. STATEMENT OF THE FACTS**

### ***A. The correct patent term adjustment and the basis or bases under §1.702 for the adjustment***

Pursuant to §§ 1.702(a) and (b) and §§ 1.704(b) and (c)(10), Applicant submits that the total correct patent term adjustment for the present ‘197 Application should be 946 days plus the amount of days beginning on the date following the filing of this Application, until the date the ‘197 Application issues as a patent. As discussed in further detail below, this number is derived from the sum of the Office’s delay calculated from §§ 1.702(a-e) (the sum of 625 days + 501 days and counting until the issuance of the present patent), minus the sum of Applicant’s delay calculated from §§ 1.704 (the sum of 87 days + 59 days + 34 days).

For the Commissioner’s convenience, Applicant presents the following table illustrating the relevant dates and delays attributable to the USPTO and to Applicant under 37 C.F.R. §§ 1.703 and 1.704, respectively. The transaction history of the present application as reported in PAIR, which shows all of the dates on which transactions took place in the present application (including those dates and transactions not discussed here because they do not involve delay), is attached as Appendix 1.

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Date	Event	USPTO Delay (and relevant section of the CFR)	Applicant Delay (and relevant section of the CFR)
7-16-2009	Applicant files Application for Patent Term Adjustment	501 days plus the number of days from the day after this date until the date the patent issues  (§ 1.703(b) and § 1.703(b)(4))	
7-14-2009	Mail date of the entry of Applicant’s 312 Amendment	↑	34 days  (§ 1.704(c)(10))
6-11-2009	Applicant files 312 Amendment	↑	
4-17-2009	Mail date of Notice of Allowance	↑	
3-9-2009	Applicant files amendment after final Office Action	↑	59 days  (§ 1.704(b))
10-9-2008	Mail date of final Office Action	↑	
7-3-2008	Applicant files response to non- final Office Action	↑	87 days  (§ 1.704(b))
2-22-2008	Date triggering the beginning measurement of USPTO delay under 37 C.F.R. § 1.703(b)	↑	
1-7-2008	Mail date of non-final Office Action	625 days  (§ 1.703(a))	
2-22-2005	Present application completes § 371 requirements		

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***B. Delay attributable to the USPTO (the relevant dates as specified in §§1.703(a) through (e) for which an adjustment is sought)***

Applicant respectfully submits that the total delay attributable to the USPTO under 37 C.F.R. § 1.703 is 1126 days, plus the number of days from the day following the filing of this Application to the day that the '197 Application issues as a patent.

The delay attributable to the USPTO stems from (1) a delay of 625 days under 37 C.F.R. § 1.702(a)(1); and (2) a delay of 501 days (and counting) under 37 C.F.R. § 1.703(b). Regarding the first, 625 day, delay, Applicant notes that the present application fulfilled the requirements of 35 U.S.C. § 371 on February 22, 2005. However, the first Office Action did not issue in the present application until January 7, 2008. 37 C.F.R. § 1.702(a)(1) specifies in relevant part that USPTO delay will be calculated as “[t]he number of days...in the period beginning on the day after the date that is fourteen months after the date on which the application ... fulfilled the requirements of 35 U.S.C. 371 and ending on the date of mailing of [ ] an action under 35 U.S.C. 132.” 625 days passed between the fourteen-month anniversary of the present application’s fulfillment of the requirements of 35 U.S.C. § 371 (April 22, 2006) and the date that the January 7, 2008 Office Action was mailed (including the date of mailing of the Office Action). Accordingly, this period accounts for the first 625 days of USPTO delay.

The second USPTO delay of 501 days (and counting) is attributable to 37 C.F.R. § 1.703(b), which specifies in relevant part that USPTO delay includes “the number of days...in the period beginning on the day after the date that is three years after the date on which the...national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date that the patent was issued.” Accordingly, this period of USPTO delay began

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the day after February 22, 2008. Because the nine days between the filing of the Notice of Appeal on April 9, 2009 and the mailing of the Notice of Allowance on April 17, 2009 are not included in the calculation of the USPTO's delay (37 C.F.R. § 1.703(b)(4)), the USPTO delay under 37 C.F.R. § 1.703(b) is 501 days as of the date that the present Application is being filed. This delay will continue to increase until the '197 Application issues as a patent.

None of the USPTO delay under 37 C.F.R. §§ 1.703(a)(1) and 1.703(b) overlap with each other, and thus the total amount of USPTO delay is the sum total of the delay under each of these sections, consistent with the recent court ruling in *Wyeth v. Dudas*. 580 F. Supp. 2d 138 (Dist. D.C., September 30, 2008). In *Wyeth*, the court rejected the USPTO's previous position that the entire period during which an application is before the USPTO is considered to be part of the period of time under § 1.703(b) for purposes of determining overlap with § 1.703(a). In particular, the court held that "[t]he only way that periods of time can 'overlap' is if they occur on the same day." *Id.* at 141. Accordingly, in the present '197 Application, the period of delay attributable to the USPTO under § 1.703(a) does not overlap the period of delay under § 1.703(b) because the § 1.703(a) delay occurs in its entirety prior to the February 22, 2008 date that the time period under § 1.703(b) starts. Thus there is no calendar day that has been counted as both delay under § 1.703(b) and delay under § 1.703(a).

Accordingly, Applicant respectfully submits that the delay attributable to the USPTO under 37 C.F.R. § 1.703 in the present '197 Application is 1126 days, plus the number of days from the day following the filing of this Application to the day that the '197 Application issues as a patent.

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***C. Delay attributable to Applicant (any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination as set forth in § 1.704)***

Applicant respectfully submits that the total delay attributable to the Applicant under 37 C.F.R. § 1.704 is 180 days. This delay stems from (1) an 87 day delay between the USPTO's mailing of the January 7, 2008 Office Action and Applicant's response; (2) a 59 day delay between the USPTO's mailing of the October 9, 2008 Office Action and Applicant's response; and (3) a 34 day delay between Applicant's June 11, 2009 filing of a § 312 Amendment and the USPTO's response to the 312 Amendment.

Regarding the first two delays ((1) and (2) above), 37 C.F.R. § 1.704(b) in relevant part states that an Applicant incurs delay equal to the "cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection." Applicant responded to the January 7, 2008 Office Action on July 3, 2008, and thus incurred an 87 day delay (calculated beginning day after the April 7, 2008 3-month date for responding to the Office Action). Applicant responded to the October 9, 2008 on March 9, 2009, thereby incurring a delay of 59 days (calculated beginning the day after the January 9, 2009 3-month date for responding to the Office Action). Hence, Applicant's total delays encompassed by 37 C.F.R. § 1.704(b) is 146 days.

Regarding the third delay ((3) above), 37 C.F.R. § 1.704(c)(10) in relevant part states that when an Applicant submits a § 312 Amendment, it incurs delay equal to "[t]he number of days...beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the...notice in response to the amendment under § 1.312." In the present

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'197 Application, Applicant submitted a § 312 amendment on June 11, 2009 and the USPTO mailed its response on July 14, 2009. Thus, Applicant incurred a delay of the 34 days between these two dates (inclusive) under 37 C.F.R. § 1.704(c)(10).

Applicants respectfully submit that the submission of the Notice of Appeal and Petition for Extension of Time on April 9, 2009 do not constitute delay under 37 C.F.R. § 1.704(c)(10) because those filings do not represent a failure to engage in reasonable efforts to conclude prosecution of the application. 37 C.F.R. § 1.704(a). In particular, the Notice of Appeal and Petition for Extension of time were required to maintain the pendency of the present application because the USPTO failed to act upon Applicant's March 9, 2009 after-final Amendment in a timely manner. Had the USPTO acted upon Applicant's amendment at any time during the month between the filing of the amendment and the filing of the Notice of Appeal, then the Notice of Allowance would have issued prior to the April 9, 2009 filing, and thus would have negated the need for Applicant to file a Notice of Appeal or Petition for Extension of Time. Accordingly, it was the USPTO's delay, rather than Applicant's delay that led to the need for the April 9, 2009 filing. As a result, Applicant respectfully submits that the April 9, 2009 filings do not constitute a failure to engage in reasonable efforts to conclude prosecution of the application, and thus do not constitute delay under 37 C.F.R. § 1.704(c)(10).

In view of the above, the total delay incurred by Applicant in the '197 Application is 180 days (146 days under 37 C.F.R. § 1.704(b) plus 34 days under 37 C.F.R. § 1.704(c)(10).

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***D. Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer***

The present '197 Application is not subject to a Terminal Disclaimer.

***E. The adjustment as specified in 37 C.F.R. § 1.703(f) to which the present '197 Application is entitled***

The total amount of patent term adjustment is specified in 37 C.F.R. § 1.703(f) as being the period of delay attributable to the USPTO under 37 C.F.R. §§ 1.703(a-e) less the amount of delay attributable to Applicant under 37 C.F.R. § 1.704. Accordingly, the present '197 Application is entitled to 946 days of patent term adjustment plus the amount of days beginning on the date following the filing of this Application, until the date the '197 Application issues as a patent. This number is derived from the sum of the delay attributable to the USPTO under §§ 1.702(a-e) (the sum of 625 days + 501 days and counting until the issuance of the present patent), minus the sum of the delay attributable to Applicant under § 1.704 (the sum of 87 days + 59 days + 34 days).

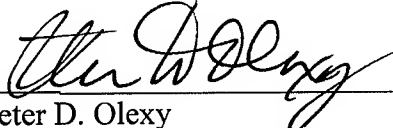


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## II. CONCLUSION

In summary, Applicant respectfully submits that it is proper that the USPTO grant Applicant's Application for Patent Term Adjustment. Favorable consideration is respectfully requested.

Respectfully submitted,

  
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**23373**

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Date: July 16, 2009

## **APPENDIX 1**



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## Transaction History

Date	Transaction Description
07-14-2009	Mail Response to 312 Amendment (PTO-271)
07-13-2009	Response to Amendment under Rule 312
06-11-2009	Amendment after Notice of Allowance (Rule 312)
04-17-2009	Mail Notice of Allowance
04-14-2009	Mail Examiner's Amendment
04-01-2009	Document Verification
04-14-2009	Notice of Allowance Data Verification Completed
04-14-2009	Examiner's Amendment Communication
04-09-2009	Notice of Appeal Filed
04-09-2009	Request for Extension of Time - Granted
03-11-2009	Date Forwarded to Examiner
03-09-2009	Amendment after Final Rejection
03-09-2009	Request for Extension of Time - Granted
10-09-2008	Mail Final Rejection (PTOL - 326)
10-08-2008	Final Rejection
08-06-2008	Date Forwarded to Examiner
07-03-2008	Response after Non-Final Action
07-03-2008	Request for Extension of Time - Granted
01-07-2008	Mail Non-Final Rejection
01-04-2008	Non-Final Rejection
02-22-2005	Information Disclosure Statement considered
01-02-2008	Case Docketed to Examiner in GAU
07-06-2006	Correspondence Address Change
02-01-2006	IFW TSS Processing by Tech Center Complete
02-22-2005	Request for Foreign Priority (Priority Papers May Be Included)
02-22-2005	Information Disclosure Statement (IDS) Filed
02-22-2005	Information Disclosure Statement (IDS) Filed
02-22-2005	Preliminary Amendment
02-01-2006	Case Docketed to Examiner in GAU
08-27-2005	Cleared by OIPE CSR
02-22-2005	371 Completion Date
08-22-2005	Application Dispatched from OIPE
08-22-2005	Notice of DO/EO Acceptance Mailed
02-22-2005	Initial Exam Team nn

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